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Substitute for form 1449A/PTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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## Complete if Known

Application Number	10/544,145
Filing Date	August 2, 2005
First Named Inventor	Shyam S. Mohapatra
Art Unit	1633
Examiner Name	Scott D. Long
Attorney Docket Number	USF.T192XC1

Sheet 1 of 7

## U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.	Document Number Number - Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	U1	US-2006-0276382-A1	12-07-2006	Mohapatra	All
	U2	US-2002/0044919	04-18-2002	Yu	All
	U3	US-2005/0025742 A1	02-03-2005	Engler <i>et al.</i>	All
	U4	US-2005/0054052 A1	03-10-2005	Carr <i>et al.</i>	All
	U5	US-2005/0054053 A1	03-10-2005	Aguinaldo <i>et al.</i>	All
	U6	US-2005/0084478 A1	04-21-2005	Liu <i>et al.</i>	All
	U7	US-2005/0272650	12-08-2005	Mohapatra	All
	U8	US-4,414,150	11-08-1983	Goeddel	All
	U9	US-4,456,748	06-26-1984	Goeddel	All

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.	Foreign Patent Document Country Code <sup>2</sup> - Number <sup>4</sup> - Kind Code <sup>6</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>5</sup>
	F1	WO 04/03679 A1	04-06-2004	The Cleveland Clinic Foundation	All	
	F2	WO 2003/074561 A1	09-12-2003	Univ. of South Florida	All	
	F3	WO 03/060689 A1	10-30-2003	Imperial College Innovations Ltd.	All	
	F4	WO 2004/074314 A2	09-02-2004	Univ. of South Florida	All	
	F5	WO 2004/022003 A3	03-18-2004	Univ. of South Florida	All	
	F6	WO 2005/094120 A2	10-10-2005	Univ. of South Florida	All	
	F7	WO 90/09780 A1	09-07-1990	Danbingsyst LHK Ltd.	All	

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	U10	US-4,678,751	07-07-1987	Goeddel	All
	U11	US-4,695,623	09-22-1987	Stabinsky	All
	U12	US-4,897,471	01-30-1990	Stabinsky	All
	U13	US-5,766,864	06-16-1998	Uno <i>et al.</i>	All
	U14	US-5,770,191	06-23-1998	Johnson <i>et al.</i>	All
	U15	US-5,831,062	11-03-1998	Taylor	All
	U16	US-5,853,755	12-29-1998	Foldvari	All
	U17	US-6,120,762	09-19-2000	Johnson <i>et al.</i>	All
	U18	US-7,354,908	04-08-2008	Mohapatra <i>et al.</i>	All
	U19	US-7,118,888	10-10-2006	Mohapatra <i>et al.</i>	All

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	F8	WVO 98/02457 A1	01-22-1996	Comnaught Lab. Ltd.	All	
	F9					
	F10					
	F11					
	F12					
	F13					

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<b>Attorney Docket Number</b>	USE T192XC1

Sheet	3	of	7
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## NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	R1	AGNINOTRI, S.A. <i>et al.</i> "Recent advances on chitosan based micro- and nanoparticles in drug delivery." <i>J Control Release</i> , 2004 Nov 5, 100(1):5-28.	
	R2	AGRAWAL, G. and KANDIMALLA, E.R. "Antisense therapeutics: is it as simple as complementary base recognition?" <i>Mol. Med. Today</i> , 2000, 6:72-81	
	R3	ANTONIGOU, K.M. <i>et al.</i> "Interferons and their application in the diseases of the lung" <i>Chest</i> , 2003, 123:390-395.	
	R4	ARAI, C. and AKBUGA, J. "Preparation and in vitro transfection efficiency of chitosan microspheres containing plasmid DNA:poly(L-lysine) complexes" <i>J Pharm Pharm Sci.</i> , 2003 Sep-Dec, pp. 321-6, Vol. 6, No. 3.	
	R5	BENJAVENTE, J. <i>et al.</i> "Indiscriminate Degradation of DNAs in Interferon-Treated, Vaccinia Virus-Infected Mouse L Cells" <i>J. Virology</i> , 1984, pp. 866-871, Vol. 51, No. 3.	
	R6	DISBAL, G. <i>et al.</i> "Cloning and Characterization of a Ribose-L Inhibitor" <i>J. Biol. Chem.</i> , 1996, pp. 13338-13347, Vol. 270, No. 22.	
	R7	BRANCH, A. "A good antisense molecule is hard to find" <i>Trends in Biochem. Sci.</i> , 1990, 25:45-50.	
	R8	CEVO, C. <i>et al.</i> "Ultrasoft vesicles, transferrin-coated, have an extremely low pore-penetration resistance and transport therapeutic amounts of insulin across the intact mammalian skin" <i>Biochim. Biophys. Acta</i> , 1998, 1368:201-215.	
	R9	CHEN, J.H. "Application of cationic polymer vector for gene delivery systems" <i>Yao Xue Xue Bao</i> , 2003 Apr 38(4):316-20, abstract.	
	R10	CHEN, W.R. "Enhancement of liver cancer treatment by a chitosan derived immunoconjugate" <i>Photocahn Photobiol.</i> , 2005 Jan-Feb, 81(1):190-5, abstract.	
	R11	CHIRILA, T. <i>et al.</i> "The use of synthetic polymers for delivery of therapeutic antisense oligodeoxynucleotides" <i>Biomaterials</i> , 2002, 23:321-342.	
	R12	COOPER, E.M. <i>et al.</i> "Cells resistant to interferon $\beta$ respond to interferon $\gamma$ via the Stat-1/IRF-1 pathway" <i>Virology</i> , 1995, 211:113-122.	
	R13	COHEN, A.D. <i>et al.</i> "Modulating the immune response to genetic immunization" <i>FASEB J.</i> 1998, pp. 1614-1626, Vol. 12.	

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**INFORMATION DISCLOSURE  
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<b>Application Number</b>	10/544,145
<b>Filing Date</b>	August 2, 2005
<b>First Named Inventor</b>	Shyam S. Mohapatra
<b>Group Art Unit</b>	1633
<b>Examiner Name</b>	Scott D. Long
<b>Attorney Docket Number</b>	USF.T192XC1

Sheet 4 of 7

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	R14	<del>COLLINS, B.L. et al. "Production of infectious human respiratory syncytial virus from cloned cDNA confirms an essential role for the transcription elongation factor from the 5' proximal open reading frame of the M2 mRNA in gene expression and provides a capability for vaccine development" <i>PNAS USA</i>, 1995, 92:11563-11567.</del>	
	R15	<del>CROOKE, S.T., "Basic principles of antisense therapeutics" in <i>Antisense Research and Application</i>, Ed. by Crooke, S.T., 1998, Chapter 1, pages 1-50.</del>	
	R16	<del>DOBSON, J., "Gene therapy progress and prospects: magnetic nanoparticle-based gene delivery" <i>Gene Therapy</i>, 2006, 13:283-287.</del>	
	R17	<del>DOMACHOWSKIE, J. and ROSENBERG, H., "Respiratory syncytial virus infection: Immune response, immunopathogenesis, and treatment" <i>Clin. Microbiol. Rev.</i>, 1999, 12:298-309.</del>	
/S.L./	R18	ELLIOTT, G. and O'HARE, P., "Intercellular trafficking and protein delivery by a herpesvirus structural protein" <i>Cell</i> , 1997, 88:223-233.	
	R19	<del>ENGLEBIENNE, P., "RNase L in health and disease: What did we learn recently?" <i>J. Chronic Fatigue Syndrome</i>, 2003, 11(2):97-109.</del>	
	R20	<del>FOLDVARI, M. and MORELAND, A., "Clinical observations with topical liposome encapsulated interferon alpha for the treatment of genital papillomavirus infections" <i>J. Liposome Res.</i>, 1997, 7:115-126.</del>	
	R21	<del>FOLDVARI, M. et al., "Liposome-encapsulated prostaglandin E<sub>2</sub> in erectile dysfunction: Correlation between in vitro delivery through foreskin and efficacy in patients" <i>Urology</i>, 1998, 52(5):838-843.</del>	
	R22	<del>GOSWAMI, B.B. and O.K. SHARMA, "Degradation of rRNA in Interferon-treated Vaccinia Virus-infected Cells" <i>J. Biol. Chem.</i>, 1984, 259(3):1371-1374.</del>	
	R23	<del>GUANG LIU, W. and DE YAO, K., "Oncozan and its derivatives - a promising non-viral vector for gene transfection" <i>J Control Release</i>, 2002 Sep 18, 83(1):1-11.</del>	
	R24	<del>GUTTERMAN, J.U., "Cytokine therapeutics: Lessons from interferon <math>\alpha</math>" <i>Proc. Natl. Acad. Sci. USA</i>, 1994, 91:1198-1205.</del>	
	R25	<del>HELLERMANN, G.R. and MOHAPATRA, G.G., "Genetic therapy: on the brink of a new future" <i>Gen. Virol. &amp; Ther.</i>, 2003, 1:1.</del>	
	R26	<del>JEONG, H. I. et al., "Nitric oxide production by high molecular weight water-soluble chitosan via nuclear factor-<math>\kappa</math>B activation" <i>Int J Immunopharmacol.</i>, 2000 Nov, 22(11):923-33.</del>	

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	R27	JUMMA, W. <i>et al.</i> "Physicochemical properties of chitosan-ribose emulsions and their stability during the autoclaving process." <i>Int'l J Pharm.</i> , 1999, 183:175-184.	
	R28	KUMAR, MNV R. <i>et al.</i> "Nanoparticle-mediated gene delivery: state of the art." <i>Expert Opin. Biol. Ther.</i> , 2004, 4(8):1213-1224.	
	R29	KIM, T. H. <i>et al.</i> "Efficient gene delivery by uronic acid-modified chitosan." <i>J. Control Release</i> , 2003 Dec 12, 93(3):389-402.	
	R30	KIM, T. H. <i>et al.</i> "Electrocytolyzed chitosan-DNA nanoparticles prepared using water-soluble chitosan as a gene carrier." <i>Biomaterials</i> , 2004 Aug, 25(17):3783-92.	
	R31	KINSEY, B. <i>et al.</i> "Non-viral gene delivery to the lungs." <i>Current Gene Therapy</i> , 2005, 5:181-194.	
	R32	KORING-HOGGARD, M. <i>et al.</i> "Improved chitosan-mediated gene delivery based on easily dissociated chitosan polyplexes of highly defined chitosan oligomers." <i>Gene Ther.</i> , 2004 Oct, 11(19):1441-52.	
	R33	KUMAR, M. <i>et al.</i> "Chitosan (CN)-pDNA nanoparticles (CN) therapy for allergic asthma." <i>Genet. Vacc. &amp; Ther.</i> , 2003, 1(1):3.	
	R34	LEONG, K.W. <i>et al.</i> "DNA-polycation nanospheres as non-viral gene delivery vehicles." <i>J. Controlled Release</i> , 1998, 53:183-193.	
	R35	LI, X.-J. <i>et al.</i> "RNase I Mediates the Antiviral Effect of Interferon through a Selective Reduction in Viral RNA during Encephalomyocarditis Virus Infection." <i>J. Virology</i> , 1998, 72(4):2752-2759.	
	R36	MANSOURI, S. <i>et al.</i> "Chitosan-DNA nanoparticles as non-viral vectors in gene therapy: strategies to improve transfection efficacy." <i>Eur J Pharm Biopharm.</i> , 2004 Jan, 57(1):1-8.	
	R37	MAO, H. Q. <i>et al.</i> "Chitosan-DNA nanoparticles as gene carriers: synthesis, characterization and transfection efficiency." <i>J. Controlled Release</i> , 2001, 70(3):399-421.	
	R38	MATSEUSE, H. <i>et al.</i> "Differential cytokine mRNA expression in Dermatophagoides farinae allergen sensitized and respiratory syncytial virus-infected mice." <i>Microbes and Infect.</i> , 2000, 2:753-759.	
	R39	MOHAPATRA, S. C. "Mucosal gene expression vaccine: a novel vaccine strategy for respiratory syncytial virus." <i>Pediatr. Infect. Dis. J.</i> , 2003, 22(2 Suppl):S100-S104.	

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		MOHAPATRA, S. Poster materials presented at International RSV Conference on June 22, 2002. Washington, D.C. (9 pages, including abstract and Figures 1-4 with captions).	
	R40		
		MONTGOMERY, D. <i>et al.</i> "DNA vaccines." <i>Pharmacol. Ther.</i> , 1997, 74:195-205.	
	R41		
		OPALINSKA, J.B. and GEWIRTZ, A. "Nucleic-acid therapeutics: Basic principles and recent applications" <i>Nature Rev.</i> , 1992, 1:508-514.	
	R42		
		OPDENAKKER, G. <i>et al.</i> "Interaction of interferon with other cytokines" <i>Experientia</i> , 1989, 45:513-520.	
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		PARK, S.-Y. <i>et al.</i> "IFN- $\gamma$ enhances TRAIL-induced apoptosis through IRF-1" <i>Eur. J. Biochem.</i> , 2004, 271(21):4222-4228.	
	R44		
		PAYNE, J. <i>et al.</i> "Particle-mediated DNA vaccination of mice, monkeys and men: Looking beyond the dogma" <i>Curr. Opin. Mol. Therapeut.</i> , 2002, 4:459-466.	
	R45		
		PENG, J. <i>et al.</i> "Influence of anions on the formation and properties of chitosan-DNA nanoparticles" <i>J Nanosci Nanotechnol.</i> , 2005 May, 5(5):713-7, abstract.	
	R46		
		PERACCHI, A. "Prospects for antiviral ribozymes and deoxyribozymes" <i>Rev. Med. Virol.</i> , 2004, 14:47-64.	
	R47		
		POOGA, M. <i>et al.</i> "Cell penetration by transposons" <i>The EMBO J.</i> , 1998, 12:67-77.	
	R48		
		ROULTON, C. and SEYMOUR, J. "Key issues in nonviral gene delivery" <i>Adv. Drug Deliv. Rev.</i> , 2001, 46:187-203.	
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		SAVIKUMAR, M. <i>et al.</i> "Nanoparticle-mediated gene delivery: state of the art" <i>Expert Opin Biol Ther.</i> , 2004 Aug 4(8):1213-24, abstract.	
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/S.L./		REIS, L.F.L. <i>et al.</i> "Critical role of a common transcription factor, IRF-1, in the regulation of IFN- $\beta$ and IFN-inducible genes" <i>The EMBO J.</i> , 1992, 11(1):185-193.	
	R52		

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**Complete if Known**

Application Number	10/544,145
Filing Date	August 2, 2005
First Named Inventor	Shyam S. Mohapatra
Group Art Unit	1633
Examiner Name	Scott D. Long
Attorney Docket Number	USF.T192XC1

Sheet	7	of	7
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**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article. (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
/S.L./	R53	ROY, K. <i>et al.</i> "Oral gene delivery with chitosan-DNA nanoparticles generates immunologic protection in a murine model of peanut allergy" <i>Nat Med</i> , 1999, 5:387-391.	
/S.L./	R54	SETHI, S.K. <i>et al.</i> "Interferon-gamma (IFN-γ) down-regulates the rhinovirus-induced expression of intercellular adhesion molecule-1 (ICAM-1) on human airway epithelial cells" <i>Clin. Exp. Immunol.</i> , 1997, 110:362-369	
/S.L./	R55	SHIBATA, Y. <i>et al.</i> "Alveolar macrophage priming by intravenous administration of chitin particles, polymers of N-acetyl-D-glucosamine, in mice" <i>Infect Immun.</i> , 1997 May, 65(5):1734-41.	
/S.L./	R56	SHORT, S.M. <i>et al.</i> "Percutaneous absorption of biologically-active interferon-gamma in a human skin graft-nude mouse model" <i>Pharm. Res.</i> , 1996, 13:1020-1027.	
/S.L./	R57	SILVERMAN, R.H. "Implications for RNase L in prostate cancer biology" <i>Biochemistry</i> , 2003, 42(7):1805-1812.	
/S.L./	R58	SIMMONS, C.P. <i>et al.</i> "Mucosal delivery of a respiratory syncytial virus CTL peptide with enterotoxin-based adjuvants elicits protective, immunopathogenic, and immunoregulatory antiviral CD8 <sup>+</sup> T cell responses" <i>J. Immun.</i> , 2001, 166:1106-1113.	
abstract only	/S.L./	R59	WAN, L.Q. <i>et al.</i> "Study of the uptake of chitosan oligosaccharide nanoparticles by A549 cells" <i>Yao Xue Xue Bao</i> , 2004 Mar, 39(3):227-31, abstract.
	/S.L./	R60	WRIGHT, P. <i>et al.</i> "Evaluation of a live, cold-passaged, temperature-sensitive, respiratory syncytial virus vaccine candidate in infancy" <i>J. Infect. Dis.</i> , 2000, 182:1331-1342.
abstract only	/S.L./	R61	XIU, Q. <i>et al.</i> "Effect of intratracheally administered IL-12 recombinant adenovirus on ovalbumin induced bronchial hyresponsiveness in mouse model" <i>Chin. J. Tuberc. Respir. Dis.</i> , 2001, 24:298-301.
	/S.L./	R62	YOO, H.S. <i>et al.</i> "Self-assembled nanoparticles containing hydrophobically modified glycol chitosan for gene delivery" <i>J Control Release</i> , 2005 Mar 2, 103(1):235-43; Epub 2005 Jan 15.
	/S.L./	R63	ZHU, Z. <i>et al.</i> "Acidic mammalian chitinase in asthmatic Th2 inflammation and IL-13 pathway activation" <i>Science</i> , 2004, 304:1678-1682.
	/S.L./	R64	ZOON, K.C. "Human interferons: Structure and function" <i>Interferon</i> , 1987, 9:1-12.
	/S.L./	R65	Copy of European Patent Office Summons to attend oral proceedings pursuant to Rule 115(1) EPC, dated October 22, 2008, for corresponding EPO application no. 04711150.5.

Examiner  
Signature

/Scott Long/ (04/14/2009)

Date  
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04/14/2009

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